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Massachusetts Board of Registration in Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

1. Do Your Patients Really Know How to Use an Inhaler?

By Donald D. Accetta, MD, MPH – Physician Member of Massachusetts Board of Registration in Pharmacy

Over 50% of patients do not use their asthma inhalers properly. For many of these patients, they were never taught by the health care provider who prescribed the medication, or the health professional used faulty technique. But even when properly instructed, studies have shown that the technique deteriorates over time and needs periodic review. Mistakes range from the common (using an empty inhaler, not shaking the inhaler before each puff, spraying multiple times for one inhalation, etc) to the truly bizarre (such as the patient who kept both an inhaler and handgun under the pillow . . . you can guess the rest of this sad story). Surprisingly, there is a similar failure rate for the newer dry powder inhalers (such as Advair® and Pulmicort®). Many elderly individuals have difficulty operating some of the devices due to limited dexterity.

Metered dose inhalers (MDI) contain the medication either as a suspension (needs to be shaken before each activation) or solution (no shaking needed). The MDI can be activated as often as every 15-20 seconds.

The general technique for using an MDI is usually similar for all brands. While it is useful to read the package insert, it is better to actually see the procedure performed and then have your own technique critiqued by a knowledgeable person. The major pharmaceutical companies train all their respiratory division representatives and they, in turn, can teach other health professionals. If you ask, the representatives are generally quite willing to review the technique and give you a demonstration. The specifics of the inhaler technique will vary depending on the type of inhaler used (suspension, solution, dry powder, breath activated) and will not be reviewed here, but are enclosed as an insert in all inhalers.

There are a variety of accessory devices such as the Aerochamber®, Aerochamber with Mask®, and Inspirease®, which can be used with the MDI to assist those who have difficulty using an inhaler. These devices also generally will increase lung deposition of the drug while decreasing the amount retained in the oropharynx.

There are two relatively new inhaler devices on the market (Foradil Aerolizer®, Spiriva®), which present a rather unique problem. These two medications come as individual doses in a blister pack. They need to be inserted into the device (the Aerolizer or HandiHaler®, respectively), crushed, and then inhaled. There have been reports of patients swallowing rather than inhaling these medications. Thus, the pharmacist should make certain that instructions for usage are clear and that the patient understands that these are to be inhaled (see the "Patient Safety Tips of the Month" article on page four of this *Newsletter* for additional information).

2. Letter from the President

By Karen Ryle, RPh, MS, President

In my previous letter, I promised to update you on the recommendations from the National Association of Boards of Pharmacy® (NABP®) Task Force to Best Reduce Medication Errors in Community Pharmacy Practice. Since the recommendations are quite lengthy, I will only share some of the highlights.

Recommendation: NABP will work with the states to enact "peer review programs and freedom from discovery protection" regulation and legislation to encourage the reporting, data collection, and analysis of medication errors.

Recommendation: NABP will aggressively pursue Food and Drug Administration (FDA) to prevent the use of product nomenclature, packaging, and labeling that may significantly contribute to medication errors.

Recommendation: NABP will work with the schools and colleges of pharmacy to incorporate patient safety and quality into the curriculum of pharmacy, nursing and medical schools. NABP will explore the possibility of incorporating specific competency statements regarding the National Boards of Pharmacy Licensure Examination and a request will be forwarded to the Pharmacy Technician Certification Board concerning the Pharmacy Technician Certification Examination

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New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

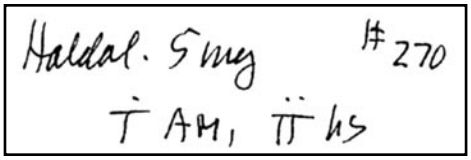
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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Recommendation: NABP will work with stakeholders to create and implement national patient safety goals targeted specifically for community pharmacy practice.

Recommendation: NABP will incorporate specific competency statements regarding patient safety into the North American Pharmacist Licensure Examination™ and a similar request to incorporate into the Pharmacy Technician Certification Examination.

As you can see we continue to work on patient safety initiatives in Massachusetts and nationally.

For a complete list of the recommendations, visit www.nabp.net.

3. Pharmacy Technician Update

To date, the Massachusetts Board of Registration in Pharmacy has registered 6,450 pharmacy technicians, many of whom are also certified by the Pharmacy Technician Certification Board (PTCB). PTCB's governing organizations are the American Pharmacists Association, the American Society of Health-System Pharmacists, the Illinois Council on Health-System Pharmacists, the Michigan Pharmacists Association, and NABP. Visit www.ptcb.org.

4. Board Adopts New Regulations to Improve Patient Outcomes

This article also appeared in the April 2005 Newsletter.

On January 14, 2005, regulations became effective that will require all pharmacies operating in Massachusetts to establish "Continuous Quality Improvement (CQI) Programs" by December 31, 2005. These regulations may be found on the Board's Web site at: www.mass.gov/dpl/boards/ph/cmr/24715.htm.

These mandated programs will require each pharmacy to establish a CQI program "for the purpose of detecting, documenting, assessing and preventing Quality-Related Events (QREs)." At a minimum, a CQI program shall include provisions to designate an individual or individuals responsible for monitoring CQI program compliance with the requirements of 247 CMR 15.00; identify and document QREs; minimize impact of QREs on patients, analyze data collected in response to QREs to assess causes and any contributing factors; use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and provide ongoing professional education at least annually in the area of CQI to pharmacy personnel. The Board encourages anyone with questions about how to establish a CQI program to contact the Board's CQI Coordinator, Leo McKenna, RPh, PharmD, at leo.mckenna@state.ma.us or 617/973-0953.

5. Patient Safety Tips Of The Month

By Karen Ryle, President

1. Look-alike, sound-alike drug errors with Reminyl and Amaryl causes name change

Mixups between **Reminyl®**(galantamine) and **Amaryl®** (glimepiride) have contributed to a name change in Reminyl. At first glance, Amaryl and Reminyl may seem sufficiently different, but when poorly handwritten, they look remarkably similar.

The overlapping dosage strength (4 mg) and frequency of dosing likely contributed to these errors. The adverse events caused by the mix-ups included severe hypoglycemia and hypoglycemia-associated complications.

According to Ortho-McNeil Neurologics, Inc, two deaths have been reported where Amaryl was incorrectly dispensed and administered instead of the prescribed Reminyl.

Ortho-McNeil announced in April that it will soon market galantamine under the brand name **Razadyne®** in an effort to stop mix-ups between the Alzheimer's disease product and the diabetes drug **Amaryl.**

2. Important need for Patient Counseling

FDA has recently alerted health care providers involving the inadvertent oral administration of Foradil Aerolizer and Spiriva HandiHaler capsules for inhalation. In total FDA has received 32 cases. Although most cases did not indicate an adverse event, one case reported difficulty breathing following oral ingestion, one reported hospitalization due to chronic obstructive pulmonary disease exacerbation, and there was one unrelated death.

The unintentional oral administration stems from the fact that these capsules resemble those typically taken orally. Swallowing the capsules for inhalation, rather than using the capsule via the appropriate inhalation device may lead to delayed onset of action, reduce efficacy, and inadequate drug delivery.

While FDA is working with the manufacturer on labeling and packaging changes to minimize potential user error and maximize patient safety, FDA offers the following suggestions:

- Counsel the patient about potential confusion and ways to avoid it.
- Advise health care providers to avoid dispensing the capsules for inhalation separately from the inhalation device.
- Advise patients who are using oral medication to store the capsules for inhalation together with the inhaler in a location where the capsules are unlikely to be confused with the oral medications.
- Circle or otherwise highlight the **"For Inhalation Use Only"** statement on the product package and container if possible.

For more information, please visit www.fda.gov.

6. NABP Announces Pharmacist Self-Assessment Mechanism

The Pharmacist Self-Assessment Mechanism™ (PSAM™) is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base. The PSAM consists of 100 multiple-choice questions and is divided into three sections of equal length. It costs $75 to take the PSAM. Pharmacists who complete all three sections of the PSAM will receive a Record of Completion stating their name and date of completion. The pharmacist should print this report and keep it for his or her records.

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Question: Who should take the PSAM?

Answer: The PSAM is applicable to general pharmacy practitioners in all settings. However, anyone who is interested may register and take the PSAM. There are no eligibility requirements to take the PSAM.

Question: How do pharmacists benefit from the PSAM?

Answer: To benefit pharmacists and serve as a learning tool, the end of each section offers a feedback loop, which displays each question, the answer selected, the correct answer, a brief rationale, and a reference where more information relating to the topic may be obtained.

Question: How is performance on the PSAM evaluated?

Answer: Upon completion of the PSAM, pharmacists will receive an unidentified Achievement Report indicating the percentage of questions answered correctly in each of the five content areas as well as the overall percentage of questions answered correctly. The Achievement Report is separate from the Record of Completion and has no identifiers of the test taker. **Neither the Achievement Report nor the Record of Completion will be provided to any other party**.

Question: Do pharmacists get to review the questions?

Answer: Yes, pharmacists will be able to review the questions in the feedback loop. However, "going back" during the PSAM is not permitted. For additional information please visit NABP's Web site at www.nabp.net.

7. Massachusetts Professional Recovery System

Program for Chemically Dependent Pharmacists and Allied Health Professionals

"*Licensed professionals reaching out to help other licensed professionals cope with alcohol and drug problems"*

For **confidential** information please contact Massachusetts Professional Recovery System Coordinator (MPRS) Tim McCarthy at 617/973-0910, or visit the MPRS Web site at www.mass.gov/dpl/services/mprs.htm.

8. Patient Adherence: 'A Shared Responsibility'

By Leo McKenna, PharmD, CQI Surveyor, and Jennifer Q. Weng, PharmD Candidate, MCPHS

Patient medication adherence is a major concern in today's health care delivery system. Patient adherence studies have shown that medication non-adherence can lead to unnecessary hospitalization and preventable harm to the patient, which can also have a substantial impact on health care costs.[1] Approximately $100 billion annually in direct and indirect costs are attributed to patient non-adherence.[2] Non-adherence can result from a variety of factors such as the cost of medications, the duration of therapy, and poor prescriber communication leading to under- or over-utilization of a medication to name a few.[3] Patients need to be educated about the benefits of properly taking their prescribed medication. The pharmacist can play a vital role in the shared responsibility of promoting patient adherence by educating the patient and monitoring prescription adherence. Providing patients with accurate information on the "why, what, and how" to properly take a medication helps promote reassurance and confirmation of reasonable expectations.

Patient counseling is an important function that should be performed on all new and refilled prescriptions. It allows the pharmacist to educate the patient on the proper use of his or her medication, what outcomes to expect, and how to react should adverse side effects occur. Counseling not only provides patient education, but it also allows the pharmacist to monitor for patient adherence so vital adjustments can be made to ensure safe continuance of therapy. In addition to patient counseling, pharmacists should also employ different strategies to help improve patient adherence. These strategies can include the use of refill reminder phone calls or e-mails, the use of pill organizers or medication reminder charts, and reinforcement.[2] The pharmacists' impact in reducing unnecessary hospitalizations and associated costs is enormous and can only be achieved one patient at a time. This one-on-one relationship with patients will build a strong ongoing trust that will promote individual health and create long-lasting relationships that will also strengthen our profession. Building alliances with consumers also serves the interest of making them better partners in their drug therapy.

[1] World Health Organization. Adherence to Long-term Therapies: Evidence for Action, Genevea Switzerland: WHO; 2003. Available at www.who./int/chronic_conditions/adherencereport/en. Accessed June 1, 2005.

[2] APhA. *Medication Compliance-Adherence-Persistence (CAP) Digest*. Washington, DC: APhA; 2003.

[3] APhA, *Highlights Newsletter*, October 2004, Volume 7, Number 4.

9. Compounded Events While Compounding a Prescription

Leo McKenna, PharmD, CQI Surveyor, and Jason Arruda, PharmD Candidate, Northeastern University

A recent Quality Related Event (QRE) reported to the Board, involving a compounded prescription that called for hydrocortisone powder as the active ingredient, was inadvertently compounded with testosterone powder. This unfortunate error resulted in harm to a 21-month-old male who experienced various adverse effects consistent with the diagnosis of precocious sexual development. This QRE serves as a reminder to pharmacists that all staff involved in compounding should be trained on a continuous basis in proper techniques of compounding and to incorporate adequate safety barriers when compounded products are requested. The same can be said by the United States Pharmacopoeia (USP) who, this July, will unveil a new Chapter that outlines **Quality Control in Pharmacy Compounding.**[1]

This QRE had several root contributors to systems involving **product selection, product processing, product verification and counseling.** The first, product selection, involved look-alike products hydrocortisone powder and testosterone

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powder that are packaged similarly causing a potential error in product selection. A safety barrier to consider would be the separation of products that have similar packaging or are considered high-alert ingredients. The implementation of such a barrier would add a "thinking step" to assure that the right product is selected. **Product preparation**: before a product is prepared all ingredients should be checked against the ingredients listed on the original prescription confirming that proper ingredients and concentrations have been selected. **Verification process**: This QRE enforces the idea that during the verification process all ingredients follow the finished compounded prescription with corresponding strengths, quantities, and calculations utilized. This provides an additional quality assurance check that the proper ingredients and concentrations were executed during product preparation. **Counseling**: the provision to counsel a patient or patient's agent, is an opportunity to discuss the expected benefits, possible negative outcomes and proper adherence to a product as well as answer questions and concerns the patient may have with the product. In this case counseling may have alerted the patient's representative to call and discuss the negative outcomes that occurred earlier in the process of discovering the QRE and may have limited the time the patient was exposed to the unintended product.

(Pharmacists should also be reminded that all compounding activities must be in compliance with **current USP standards** [see 247 CMR §9.01(3)]).

[1] Pharmacists' Pharmocopeia, www.usp.org/products/pharmacistsPharm.html

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